



Society Of Infectious Diseases Pharmacists

June 29, 2000

Board of Directors

Robert Stevens, PharmD
President
Memphis, TN

Peggy Carver, PharmD
President-Elect
Ann Arbor, MI

Douglas Fish, PharmD
Secretary/Treasurer
Denver, CO

James Garrelts, PharmD
Immediate Past President
Wichita, KS

Charles Ballow, Pharm.D., M.S.
Director at Large
Buffalo, NY

Stephen Piscitelli, PharmD
Director at Large
Bethesda, MD

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852.

Re: Docket No. 00N-1256 – Over-the-Counter Drug Products, Public Hearing

To Whom It May Concern:

In the announcement of the aforementioned docket published in the Federal Register on April 27, 2000, a number of discussion points were raised regarding "Criteria" for allowing drugs or drug classes to be included as Over-the-Counter (OTC) products. As mentioned in this document, the risks and benefits of inclusion of antimicrobial agents into the category of OTC products were discussed at the public hearing on June 28-29, 2000.

The Society of Infectious Diseases Pharmacists (SIDP) would like to urge the agency to maintain antimicrobial agents as "prescription drugs." The rationale for our recommendation is discussed below.

As discussed in the docket, there are tremendous risks associated with widespread and misuse of antimicrobial agents, not to the consumers alone, but to society as a whole, in the US and globally. On June 12, 2000, the World Health Organization (WHO) along with the Centers for Disease Control and Prevention (CDC) issued a press release regarding the threats of microbial resistance globally that has resulted in significant public health and economic stresses to many countries, including the US. Misuse of antimicrobials by both the medical and veterinary professionals was cited as the major source of this problem.

In developed countries like the US, misuse is primarily a result of overprescribing of antibiotics for unwarranted indications (such as for the common cold or viral upper respiratory tract infections) and over usage of broad spectrum antimicrobial agents. These misuses have led to increasing resistance in the community as seen with the emergence of multiply drug resistant strains of *Streptococcus pneumoniae* and *Hemophilus influenzae*. Some of these organisms have developed resistance to various major classes of antibiotics, including the penicillins, cephalosporins, quinolones, macrolides, and sulfonamides. In the nosocomial setting, the overuse of beta-lactam antibiotics and vancomycin has led to emergence of resistant organisms such as vancomycin-resistant enterococci (VRE) and extended spectrum beta-lactamase producing gram-negative bacilli. There are currently limited alternative treatments for these infections, thus resulting in significant morbidity and mortality. In addition, infectious diseases caused by these pathogens often prolong

1717 West 6th Street
Suite 214
Austin, TX 78703

Phone: 512/708-0611
Fax: 512/708-0627
Email: IDPharm@aol.com

00N-1256

CH 149

hospitalization, increase iatrogenic complications, and inevitably, increase health care costs.

The WHO and the CDC recommended improvement of education to prescribers on the judicious and responsible use of antimicrobial agents as one measure to reducing drug resistance. This recommendation is supported by the American Medical Association and the Infectious Diseases Society of America. The need for this type of education implies that the current problems with drug resistant are largely due to inappropriate prescribing of the currently available antimicrobial agents by health care professionals. In many cases, overprescribing of antibiotics stems from consumer pressure. In other cases, inadequate consumer education and non-adherence to their prescribed medications could also be promoters of drug resistance.

The switch of antimicrobial agents from prescription to OTC status will give consumers the responsibilities of their own antimicrobial consumption and selection. In general, consumers perceive that all infections (including viral infections) are treatable by antibacterial agents. In addition, it is commonly believed that treatment at the first sign of infection may result in earlier symptom relief, which translate into less days loss from work and school. Easy access to antibiotics will certainly increase inappropriate consumption of these agents, not to mention the danger of self-diagnosis and selection of an inappropriate agent. All these will further promote misuse of antibiotics and development of more resistant strains in the community.

The availability of antimicrobial agents without the need of a prescription has been the major cause of antibiotic resistance in many countries. Some of these include multiply-drug resistant *Salmonella typhi* and *Neisseria gonorrhoeae*. The US should not adapt the policies and practices of these countries in which increased prevalence of antimicrobial resistance occurred, in part, from uncontrolled use of antiinfective drugs.

With the above reasons, it is the position of the SIDP that allowing antimicrobial agents to be purchased over-the-counter can be detrimental to the consumers and to the society by further accelerating development of more resistant strains of human pathogens in the community. We cannot see any benefit of having this drug class as OTC products. Thus, SIDP strongly urges the FDA to continue to maintain antimicrobial agents under the regulation of prescription medications.

The SIDP is committed to develop interdisciplinary statements on policy and guidelines for the rational use and evaluation of antiinfectives. As such, we appreciate the opportunity to respond to this important issue.

Sincerely,

A handwritten signature in cursive script that reads "Robert C. Stevens". The signature is written in dark ink and is positioned above the printed name and title.

Robert C. Stevens, Pharm.D.
President, SIDP